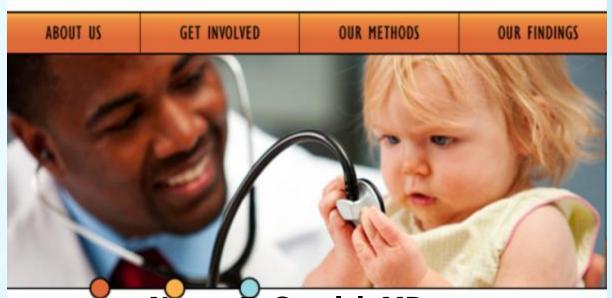
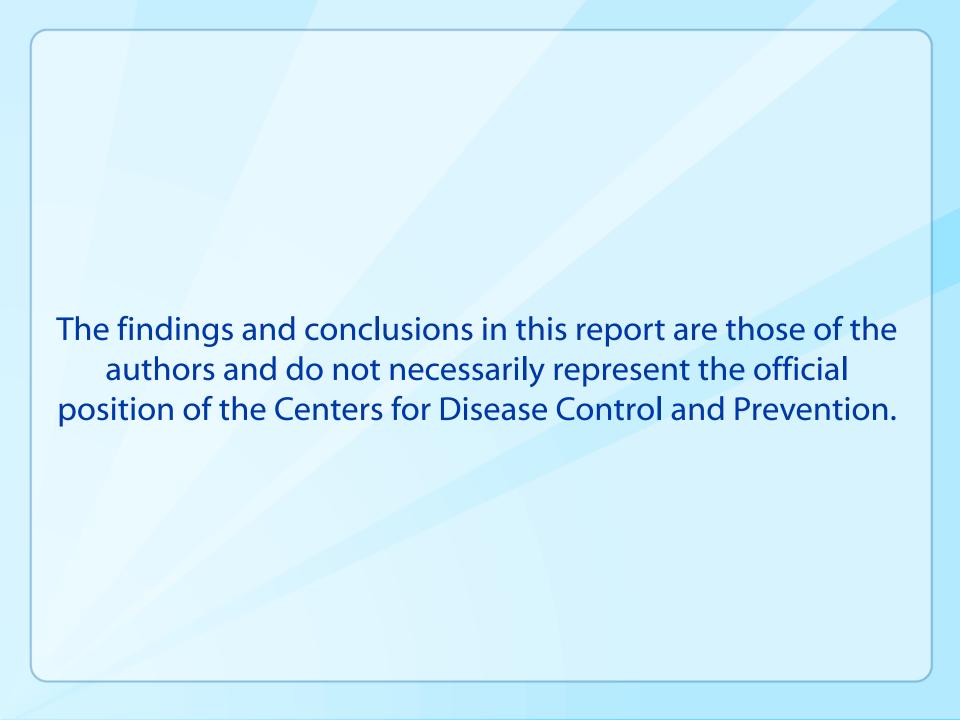
# Laboratory Medicine Best Practices (LMBP) Initiative Update

Clinical Laboratory Improvement Advisory Committee Meeting August 30, 2012



Nancy E. Cornish MD,
CDC Division of Laboratory Science and Standards



## **Questions for CLIAC Consideration**

- How can we generate new topics for discovery of laboratory best practices?
- What topic suggestions do you have?
- How can laboratory professionals become more engaged in quality improvement studies that...
  - advance on-site laboratory improvements?
  - support the broader evidence base for systematic reviews?
- What additional tutorials would help laboratory professionals learn about evidence-based practices and quality improvement study strategies?
- How can we more broadly communicate/disseminate best practices recommendations?

## **Previous Presentations To CLIAC**

Date	Presenter	Affiliation	
Sept 2006	Dr. Joe Boone	CDC	
Feb 2007	Dr. Julie Taylor	CDC	
Sept 2007	Dr. Susan Snyder	CDC	
Sept 2008	Dr. Joe Boone	CDC	
Feb 2009	Dr. Ed Liebow	Battelle	
March 2011	Dr. Robert Christenson, Ms. Diana Mass	LMBP Workgroup	



#### **History/Goals**

- □ CDC initiative, beginning in 2006 with contract assistance from Battelle
- Establish and use <u>transparent</u>, <u>systematic</u> review methods to evaluate evidence of laboratory practice effectiveness, especially in the pre- and post-analytical phases
- Improve healthcare quality and patient outcomes\* through dissemination of evidence reviews of effectiveness which identify evidence-based laboratory medicine "best practices"
- Increase participation of laboratory professionals in quality improvement research and data collection

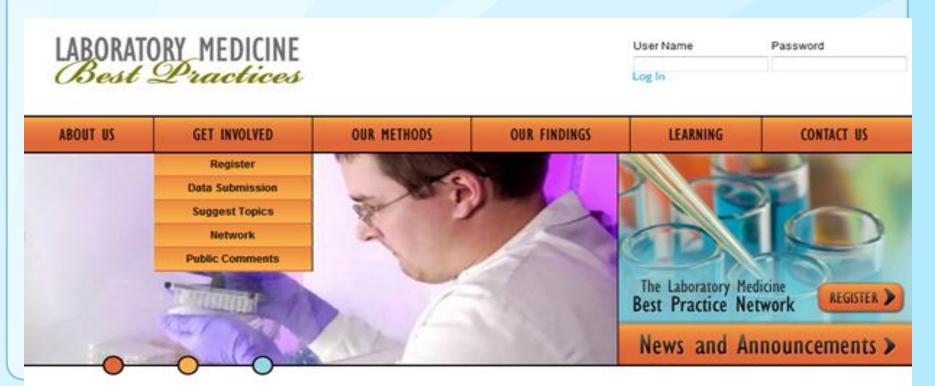
\*Following Institute of Medicine's quality domains: safe, timely, effective, efficient, equitable, and patient-centered

LABORATORY MEDICINE Best Practices

## www.futurelabmedicine.org

#### **Information and Activities:**

- Tutorials, technical reports, systematic review findings
- Calls for evidence and for review topics
- Announcements of publications and meeting presentations

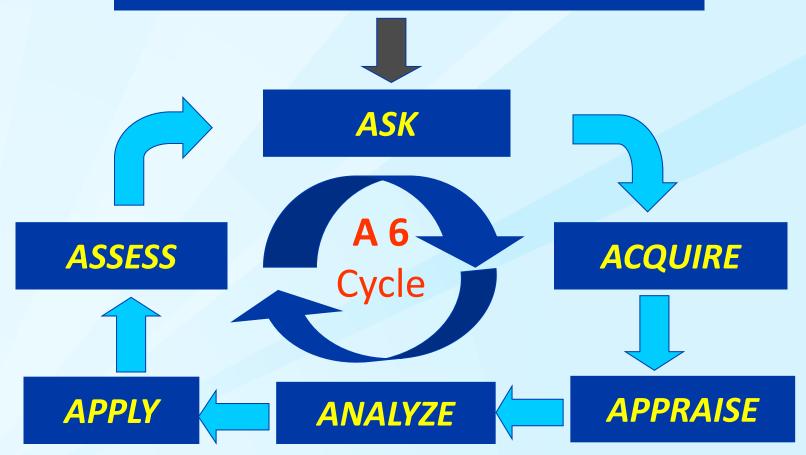




#### LMBP A6 Method

Clin. Chem. June 2011, Vol. 57(6): 816-825. Epub Apr 22, 2011

#### **QUALITY GAP/POLICY PROBLEM**



# Accomplishments 2011-2012

## Four Published Reviews, 2012

Effectiveness of Barcoding for Reducing Patient Specimen and Test Identification Errors: A Laboratory Medicine Best Practices Systematic Review and Meta-Analysis. [Snyder SR, Favoretto AM, Derzon JH, Shaw C, Baetz RA, Christenson RH, Mass D, Fantz C, Raab S, Tanasijevic M, Kahn S, Liebow EB.] Clinical Biochemistry.

http://dx.doi.org/10.1016/j.clinbiochem.2012.06.019

Effectiveness of Practices to Reduce Blood Culture Contamination: A Laboratory Medicine Best Practices Systematic Review and Meta-Analysis [Snyder SR, Favoretto AM, Baetz RA, Derzon JH, Madison B, Mass D, Shaw C, Layfield C, Christenson R, Liebow EB] Clinical Biochemistry.

http://dx.doi.org/10.1016/j.clinbiochem.2012.06.007

# Published Reviews, 2012, cont'd

- □ Effectiveness of Automated Notification and Customer Service Call Centers for Timely and Accurate Reporting of Critical Values: A Laboratory Medicine Best Practices Systematic Review and Meta-Analysis [Fontanesi J, Derzon JH, Favoretto AM, Baetz RA, Shaw C, Thompson P, Mass D, Christenson R, Snyder SR, Epner P, Liebow EB] Clinical Biochemistry. doi:10.1016/j.clinbiochem.2012.06.023
- Effectiveness of Practices to Reduce Blood Sample Hemolysis in Emergency Departments: A Laboratory Medicine Best Practices Systematic Review and Meta-Analysis [Heyer NJ, Derzon JH, Winges L, Shaw C, Mass D, Snyder SR, Epner P, Nichols JH, Gayken JA, Ernst D, Liebow EB] Clinical Biochemistry, doi:10.1016/j.clinbiochem.2012.08.002,

# **Systematic Reviews In Progress**

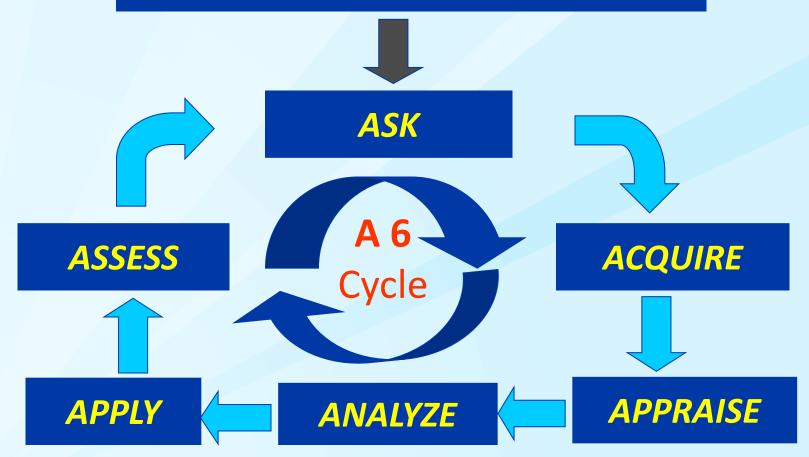
- Use of Cardiac Biomarkers to Diagnose N-STEMI Myocardial Infarction in the Emergency Department
- American Society for Microbiology (ASM)
   Collaboration projects
  - Rapid diagnosis of blood stream infections
  - Urine collection and transport
  - C. difficile diarrhea diagnosis

# Systematic Reviews In Progress in Conjunction with ASM

- Blood stream infections- Rapid Diagnostic
   Methods conducted by CDC/Battelle with ASM expertise (At "Analyze" Step)
- Urine Transport conducted by ASM with CDC guidance (At "Acquire" Step)
- Clostridium difficile planned by ASM with CDC guidance (Starting "Ask" Step)

# **Evidence Based Approach-Systematic Reviews And The ASM Collaboration**

**QUALITY GAP/POLICY PROBLEM** 



## **CDC & ASM Collaboration Timeline**

Date	<b>Event/Activity</b>	Comments
May 2010	LMBP presentation at ASM annual meeting	ASM leadership identified team to select & prequalify topics (ASM 7)
Feb 2011	ASM-CDC-Battelle workshop	Training on A6 method; ASM selected 3 topics
2011-2012	ASM staff/volunteers "shadow" review process for 1st topic	Rapid ID of blood stream infection review near completion
2012 -	ASM collaborating with CDC on 2 <sup>nd</sup> topic	Urine collection and transport
2013 -	ASM takes lead for 3 <sup>rd</sup> topic in collaboration with CDC	C.difficile diarrhea diagnosis



# LMBP Team-ASM 7 with CDC/Battelle



### **CDC & ASM Collaboration**

- ASM
  - Committed to A-6 method; may supplement Cumitechs
  - Will publish findings in Clinical Microbiology Reviews
  - New 'Evidence-based Practice Guidelines Committee' (per ASM Professional Practice Committee) includes "ASM 7"
  - Dr. Mark LaRocco hired as Review Coordinator for ASM Expert Panel's systematic review work
  - Librarian hired to support literature searches
- CDC
  - Liaisons ensure fidelity to A-6 methods
  - LMBP workgroup reviews findings and recommends best practices

# **Systematic Review Topic Pipeline**

Calling for suggestions:

- on LMBP website
- when presenting LMBP projects at meetings
- from LMBP Workgroup
- from CDC and Battelle staff
- from CLIAC members

# **Topic Identification and Selection Process: Guiding Principles**

- Define a quality issue with an opportunity for improvement consistent with the six IOM healthcare quality aims\*
- Frame it with one, focused review question for a defined patient population
- Identify at least three practices with potential to improve performance or quality outcomes associated with the defined quality issue

\* Safe, Timely, Effective, Efficient, Equitable, and Patient-centered

# **Topic Identification and Selection Process: Guiding Principles**

- Target outcome measures to assess practice effectiveness and have broad, stakeholder interest
- Evidence for effectiveness should be available from published sources (unpublished sources also possible using A-6)
- Prefer topics that are pre- and post-analytic issues
  - areas of most significant quality challenges

## The LMBP Analytic Framework-ASK Step

Quality Problem

Clear statement of issues related to the topic

Preventability /

Improvement
Measurable gap
targeted for
improvement

Interventions/
<a href="Practices">Practices</a>

May impact quality gap

Intermediate Outcomes

Measures that may precede or lead to health outcomes

Harms
Adverse
effects of
practices

Health
/Healthcare
<u>Outcomes</u>

End results of practices that directly impact patients and patient care

#### **ASK Step**

**Review Question**: Among hospitalized patients, what practices are effective for reducing blood culture contamination?

#### Quality Problem

Pre-collection practices (aseptic technique, agent, proper drying time) & collection site are sources of contamination

# Preventability / <a href="Improvement">Improvement</a>

BCC rate range: 1.1-5.2%
ASM standard is rate

not to exceed 3%

# Current Practices and Interventions

- Venipuncture vs. intravenous catheters
- Phlebotomy teams vs. non phlebotomy staff
- Prep kit vs. no prep kit

# Intermediate Outcomes

- Contamination Rate
- False positive cultures
- Re-collection
- Additional testing / follow-up associated with reevaluation
- Incorrect / delayed diagnosis

# Health / Care Outcomes

- Unnecessary additional tests
- Unnecessary antibiotic therapy
- Unnecessary hospital admissions
- Hospital acquired infections
- Increased length of stay
- Additional incremental care costs

## Associated Harms and Benefits

- Increased risk of occupational needle stick
- Patient / provider dissatisfaction



## Topics in the Pipelinefor Pre-qualification

- Lipid profile testing in cardiovascular disease patients
- Using HbA1c/measurement as a diagnostic tool
- Coagulation testing/ hypercoagulation panel
- Effective diagnosis of sepsis
- Reflex molecular testing in microbiology
- Reducing blood utilization

#### **Additional Lessons Learned**

- LMBP A6 Methods also evaluate quality improvement practices from **un**published data
- □ Builds the laboratory medicine evidence base
- □ Provides relevant data for systematic evidence reviews
- □ Data = evidence of practice effectiveness
- □ However, Many studies fail to meet minimum standards for good study design and implementation – Why?

## Common Quality Improvement Study Problems

Information commonly missing in laboratory medicine quality improvement projects (communications and journal articles)

- Sample description
- Sample selection
- Data collection method
- Statistical methods

- Intervention
- Outcome measure
- Time period
- Cause and effect

# Common Quality Improvement Study Problems, continued

- Frequently,
  - fewer than 3 articles published on same topic
  - probably due to journal's desire for unique articles
  - at least 3 studies are needed for statistical significance
- Special groups of patients missing from studies;
   e.g., children (children are not little adults)

# **LMBP Educational Activity**

A series of self-guided tutorials (with CE credit) which:

- Increase awareness about new LMBP A-6 methods for conducting systematic evidence reviews
- Increase competency for application of evidencebased principles to quality improvement (QI) projects or research

# On-Line Training for Evidence-Based Laboratory Practice

Module 1: An Overview of A-6 Methods- in use by the laboratory community https://www.futurelabmedicine.org

- Module 2: Application of A-6 Methods for Laboratory Practitioners – near completion
- Additional Modules: Concepts pending>Ideas from CLIAC members are welcomed

#### Future Focus: Apply (A5) and Assess (A6)





# "Apply"

- Apply step (A5) involves dissemination and implementation of new practice in the field
- IOM states that it takes up to 17 years for a new guideline to become standard practice
- How can more rapid adoption be encouraged?

### "Assess"

- Assess step (A6) measures the impact of the best practice recommendation on laboratory practice
  - collect measurement /data
  - submit to LMBP website
- How should QI projects be designed
  - to meet standards for systematic review
  - for inclusion in practice recommendation
  - to support A-6 cycle completion

# **Future Focus: QI Study Tools**

Completed systematic reviews = templates for QI projects in other clinical laboratories

- Optimal study design featured in Discussion of published LMBP recommendations
- Optimal study design Checklist includes all required elements discovered during previous systematic review of topic
- Optimal study design and Checklist are on LMBP website
   "QI project in a box"
- Recruit clinical laboratory sites to participate in study using "QI project in box" model

# Develop A Checklist With Required Elements For Systematic Review

LMBP Hemolysis in the ED - Quality Improvement (QI) Project/Study Summary Form

(Note: Please complete separate form for each study/evaluation you conducted)								
Background Information	QI Project/Study	QI Practice	Outcome Measures	Results/Findings				
LMBP Topic: Hemolysis in the ED  1. Problem/Quality Issue Description A. Practices (check all that apply):	QI Project Study Design/Type:     Observational     Pre-post implementation     Solit implementation (multiple sites)	10. Describe Usual Practice:	14. Outcome Measure(s) Description:	17. Results/Findings as (related to study design/outcome measure):				
Straight need venipuncture vs. IV start     Appopublish, bossa vs. distal arm     Large vs. small gauge needle/catheter     Low vs. All vacuum tubes     Syringe vs. tube when using IV start     Duration of applied tourniquet	Gase - Control Randomized assignment Other Please Describe checked design:	11. Describe Alternate/Intervention Practice:	Other – Describe:	18. Data Analysis – Statistics: ☐ Simple Association (not controlling non-test variables ☐ Associations controlling for other				
Other – Describe:  B. Personnel (check all that apply):	Facility Description (include size):     Hospital: TypeN Beds:	12. Intervention Duration Dates (pilot, pre/post, etc.) – List each phase with start and end dates:	15. Recording method (howdata was collected / note any differences between standard and test practices):  ☐ Loos of occurrence	variables  Rate Comparisons between two groups  Other  Please Describe each checked method:				
Lab prilebotomist vs. ED staff Training vs. no special training for ED staff Other – Describe:	Other - Describe:	Describe Phases:	Incident / adverse events reports     Audit – direct observation     Electronic information system monitoring     Other     Please Describe each checked method:	19. Data Analysis-Significance				
2. Submitter(s) and Org. Affiliations:	QI Project/Study Setting:     Emergency Department     Other – Describe:	13. Resource Requirements/Costs: A. Staff / Training:	16. Potential Sources of bias:	F-Test T-Test Fischer Exact Chi-square Other				
Study Dates Completed/Submitted: Completed:	8. Overall Project/Study Timeframe (include pilot projects): Start & End Dates:	B. Equipment/Supplies:	Patient characteristics: difficult / poor veins / severity of injury Tigiojo, g of staff Gauge of needle/catheter Number of tubes drawn at once Other – Describe:	Please Describe each checked method:  20. Conclusions:				
	Please Describe:	C. Other:						
Submitted to LMBP (Date):  4. Funding Source(s):  In-house  Manufacturer: Describe:  Grant/Contract: Describe:	Study Sample/Population (size and description – describe if different between compared practices)							

You can "check" boxes by double left clicking on them. If you do not have room to fill in the answer, use the next page and refer to question number.

Developed by Nickolas Heyer, Battelle Institute

## **Questions for CLIAC Consideration**

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# Interested in LMBP? Register at:

https://www.futurelabmedicine.org



Receive notification of:

- ☐ Availability of technical reports, review findings, tutorials
- ☐ Calls for evidence, topics, public feedback
- ☐ Announcements of publications and meeting participation

